DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

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October 12, 2000

WARNING LETTER NYK 2001-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas N. Stevens, President
Buffalo Welding Supply Co., Inc.
396 Grand Island Blvd.
Tonawanda, NY 14150

Dear Mr. Stevens:

Inspection of your medical gas manufacturing facility at 396 Grand Island Blvd., Tonawanda, NY, was performed September 20-26, 2000 by U.S. Food and Drug Administration (FDA) Investigators Patricia A. Clark and Tammy S. Notto. This inspection revealed Oxygen USP repacked at your facility is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) because the controls used for its manufacture, processing, packing, or holding are not in conformance with current good manufacturing practice (CGMP) regulations. Additionally, Oxygen USP repacked by your firm into high pressure cylinders is also misbranded within the meaning of Section 502(b)(2) of the Act in that its label fails to contain a statement of the quantity of the contents.

The inspection revealed numerous deviations from the CGMP regulations (Title 21, Code of Federal Regulations, Parts 210 and 211) and a labeling violation (Title 21, Code of Federal Regulations, Part 201). These deviations were included in the FDA-483, Inspectional Observations, issued at the conclusion of the inspection, and/or discussed with you during the inspection, and are as follows:

- **Calibration of the Servomex 570A Oxygen Analyzer, which is used to test the purity of filled Oxygen USP cylinders and Liquid Oxygen USP (medical gas), is not performed according to the manufacturer's current instructions [21 CFR 211.160(b)(4)].** You did not have the high purity Nitrogen required to calibrate the "zero" on the meter. Current calibration instructions call for the Servomex 570A to be zeroed with high purity nitrogen standard and spanned with high purity oxygen standard of at least 99.2%.

- **Lack of a Certificate of Analysis (COA) for the oxygen gas calibration standard used to calibrate the Servomex 570A Oxygen Analyzer [21 CFR 211.160(b)].** You did not have a certificate of analysis establishing high purity of the oxygen used to calibrate the analyzer.

Other CGMP deviations noted include the following:

- **Responsibilities and procedures applicable to the Quality Control Unit are not identified in writing [21 CFR 211.22(d)].**

- **There are no written procedures that provide a system with which the distribution of each lot of drug product can be readily determined to facilitate recall if necessary [21 CFR 211.150(b)].**

- **There are no written procedures describing the receipt, identification, storage, handling, and examination of medical gas labeling [21 CFR 211.122(a)] and [211.125(f)].**

- **There are no written procedures describing warehousing procedures, including quarantine of medical gas before release [21 CFR 211.142(a)].**

- **Written procedures describing calibration of the Servomex 570A Oxygen Analyzer and vacuum gauges are inadequate [21 CFR 211.160(b)(4)].** For example, your written procedures for calibration of the Servomex 570A are contradictory in that they contain two different methods. Furthermore, the method employed by your firm is not the current method recommended by the manufacturer. There are no instructions for calibration of gauges.

- **Written complaint handling procedures are inadequate [21 CFR 211.198].** For example, your procedures do not provide for review by the Quality Control Unit of any potential complaint involving the possible failure of medical gas product to meet specification, and a determination as to the need for an investigation.

- **Failure to conduct training in Current Good Manufacturing Practices (CGMP) for employees involved in the manufacture and distribution of medical gas [21 CFR 211.25(a)].** Although documentation of such training was supplied to the Investigators during this inspection, discussions with three of your employees involved in production of medical gas revealed no CGMP training has been given.

- **Lack of designated quarantine areas for empty cylinders, rejected cylinders, and finished medical gas product cylinders prior to release [21 CFR 211.42(c)(7)].** There are no separate and marked areas for medical gas cylinders in these various stages of production.

- **Reconciliation of the quantities of medical gas labels issued and returned is not performed [21 CFR 211.125(c)].**

- **Medical gas labels are not stored in an area limited to authorized personnel [21 CFR 211.122(d)].** Loose Oxygen USP cylinder labels were stored on a shelf in the filling area. This area is not limited to authorized employees of your firm. Persons not employed by your firm were observed in this area.

- **Failure to always obtain a valid Certificate of Analysis (COA) from your bulk supplier of Oxygen USP [21 CFR 211.84(d)(2)].** At times COA's lack the test method used by the supplier to perform the analysis.

- **Prior to 04/04/00, Batch Production Records (Daily Pumper Logs) did not contain or document all necessary pre-fill steps for Oxygen USP cylinders, specifically, cylinder evacuation [211.188(b)].**

- **Changes (crossouts) on Batch Production Records (Daily Pumper Logs) for Oxygen USP are not dated and initialed [211.188(b)].**

- **Batch Production Records (Daily Pumper Logs) for Oxygen USP are initialed or signed as having been reviewed by a Quality Control Unit representative, but are not dated [211.188(b)(1)].**

- **Batch Production Records (Daily Pumper Logs) for Oxygen USP lack copies or specimens of labeling used in production [211.188(b)(8)].**

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure all drugs manufactured and distributed by your firm meet the requirements of the Act, and associated regulations. You should take prompt action to correct these violations, and all other violations existing at your firm, and to establish procedures whereby such violations will not recur. Failure to achieve prompt correction may result in regulatory action – **without further notice**. This action may include, but is not limited to seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

Please notify this office in writing, within fifteen (15) days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to Patricia A. Clark, Compliance Officer, at the above address. If you have further questions, you may reach Ms. Clark by telephone at (716) 551-4461, ext. 3165.

Sincerely,

Robert L. Hart
Acting District Director
New York District

Attachment: Copy FDA 483